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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,827	05/24/2000	Philip N. Benfey	5914-078-999	5552

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 09/27/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/578,827

Applicant(s)

BENFEY ET AL.

Examiner

Cynthia Collins

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondenc address --**
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-25, 27 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) 22-25, 27 and 31-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The Amendment filed July 3, 2002, paper no.18, has been entered.

Claim 30 is cancelled.

Claims 22-24 and 31-33 are newly amended.

Claims 22-25, 27 and 31-33 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

The objection to claim 23 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in light of the amendment of claim 23.

Claim Rejections - 35 USC § 112

The rejection of claims 22-25 and 27 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is withdrawn in light of the amendment of claims 22 and 24 to recite that the *SHORT-ROOT* promoter consists essentially of a nucleic acid of SEQ ID NO:4.

Claims 32-33 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed January 3, 2002.

Applicant's arguments filed July 3, 2002, have been fully considered but they are not persuasive.

Applicant argues that the amendment of claims 22 and 24 to recite that the *SHORT-ROOT* promoter consists essentially of a nucleic acid of SEQ ID NO:4, and the amendment of independent claims 32 and 33 to recite that the isolated nucleic acid molecule comprises a nucleic acid sequence which hybridizes over its full length under high stringency conditions to a *SHORT-ROOT* promoter which consists essentially of the nucleic acid sequence of SEQ ID NO:4, combined with the original recitation that the isolated nucleic acid promotes stele-specific expression in the root and hypocotyl, should overcome the written description rejection (reply page 5).

The Examiner maintains that amendment of the claims to recite that the isolated nucleic acid molecule comprises a nucleic acid sequence which hybridizes over its full length under high stringency conditions to a *SHORT-ROOT* promoter which consists essentially of the nucleic acid sequence of SEQ ID NO:4, combined with the original recitation that the isolated nucleic acid promotes stele-specific expression in the root and hypocotyl, does not overcome the written description rejection of claims 32-33. The amended claim language combined with the original recitation that the isolated nucleic acid promotes stele-specific expression in the root and hypocotyl does not overcome the rejection because the specification does not describe the structure of any nucleic acid sequence which hybridizes over its full length under high stringency

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conditions to the nucleic acid sequence of SEQ ID NO:4 and that promotes stele-specific expression in the root and hypocotyl. In the absence of a structural description of hybridizing sequences that function to promote stele-specific expression in the root and hypocotyl, the invention is not described.

The rejection of claims 22-25 and 31 under 35 U.S.C. 112, first paragraph, for scope of enablement, is withdrawn in 1 is withdrawn upon further consideration and in light of the amendment of claims 22 and 24 to recite that the *SHORT-ROOT* promoter consists essentially of a nucleic acid of SEQ ID NO:4.

Claims 27 and 32-33 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid sequence of SEQ ID NO:4, and a transgenic *Arabidopsis* plant comprising a gene of interest operatively associated with a *SHORT-ROOT* promoter of SEQ ID NO:4, does not reasonably provide enablement for other promoter sequences, or other plants comprising other promoter sequences, for the reasons of record set forth in the office action mailed January 3, 2002.

Applicant's arguments filed July 3, 2002, have been fully considered but they are not persuasive.

Applicant argues that the amendment of independent claims 32 and 33 to recite that the isolated nucleic acid molecule comprises a nucleic acid sequence which hybridizes over its full length under high stringency conditions to a *SHORT-ROOT* promoter which consists essentially of the nucleic acid sequence of SEQ ID NO:4, combined with the original recitation that the

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isolated nucleic acid promotes stele-specific expression in the root and hypocotyl, should overcome the scope of enablement rejection, as one skilled in the art would recognize the washing conditions in a nucleic acid hybridization reaction as the critical feature for the stringency of hybridization, and would be able to recognize the molecule of the claimed invention based on the well known relationship between nucleic acid structure and hybridization (reply page 6). Applicant argues that one skilled in the art would recognize the claimed nucleic acid molecule on the basis of its size, ability to hybridize over its full length to SEQ ID NO:4, and its function of promoting stele-specific expression in root or hypocotyl. Applicant notes that an invention is enabled even though the disclosure may require routine experimentation to practice the invention, and that a considerable amount of experimentation is permitted if it is routine or if the specification provides sufficient guidance and direction to the experimentation. Applicant argues that the instant specification provides sufficient guidance and direction to the enable the claimed invention as it teaches how to isolate the claimed nucleic acid molecules as well as how to isolate a transgenic plant comprising the claimed nucleic acid molecules. (reply page 7).

The Examiner maintains that the amendment of independent claims 32 and 33 to recite that the isolated nucleic acid molecule comprises a nucleic acid sequence which hybridizes over its full length under high stringency conditions to a *SHORT-ROOT* promoter which consists essentially of the nucleic acid sequence of SEQ ID NO:4, combined with the original recitation that the isolated nucleic acid promotes stele-specific expression in the root and hypocotyl, does not overcome the scope of enablement rejection, because the specification does not provide sufficient guidance for one skilled in the art to determine, without undue experimentation, which

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nucleic acid sequences hybridizing under high stringency conditions to SEQ ID NO:4 would retain the function of promoting stele-specific expression in the root and hypocotyl. The Examiner maintains that the undue experimentation lies in the process of discriminating between those nucleic acids hybridizing under high stringency conditions to SEQ ID NO:4 that would be likely to retain stele-specific promoter function and those nucleic acids hybridizing under high stringency conditions to SEQ ID NO:4 that would not be likely to retain stele-specific promoter function, before such sequences are subjected to methods for testing promoter function. The Examiner maintains that the specification does not provide sufficient guidance because the specification provides only a single example of a sequence that has stele-specific promoter function, the nucleic acid sequence of SEQ ID NO:4. The Examiner maintains that the exemplification of a single sequence that has stele-specific promoter function does not provide sufficient guidance to enable nucleic acids hybridizing under high stringency conditions to SEQ ID NO:4 that have a stele-specific promoter function.

Additionally, Applicant argues that contrary to the Examiner's allegation, the specification teaches that the *SHORT-ROOT* promoter has function and drives the expression of reporter genes in *Arabidopsis* (reply page 7).

Regarding Applicant argument that contrary to the Examiner's allegation, the specification teaches that the *SHORT-ROOT* promoter has function and drives the expression of reporter genes in *Arabidopsis*, the Examiner points out that the promoter function of the *SHORT-ROOT* promoter of SEQ ID NO:4 operatively associated with a GFP reporter gene was recognized and acknowledged on page 4 of the office action mailed January 3, 2002. In light of

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the amendment of claims 22 and 24 to recite that the *SHORT-ROOT* promoter consists essentially of a nucleic acid of SEQ ID NO:4, the rejection of claims 22-25 and 31 under 35 U.S.C. 112, first paragraph, for scope of enablement, has been withdrawn *supra*.

In response to the Examiner's assertion that the specification does not teach a transgenic plant less susceptible to lodging, said plant containing a gene of interest operably linked to the *SHORT-ROOT* promoter, Applicant point out that claim 25 is drawn to a transgenic plant in which the gene of interest operably linked to the *SHORT-ROOT* promoter encodes a polypeptide that increases starch, lignin, or cellulose biosynthesis. Applicant also points out that two types of lodging, well known to those skilled in the art, may occur in a plant, stem breakage and root lodging. Applicant argues that contrary to the Examiner's assertion that the specification does not teach a transgenic plant less susceptible to lodging, the specification teaches on page 56 that genes that may be beneficially expressed in the stems of plant include those involved in starch, lignin or cellulose biosynthesis, and that one skilled in the art would recognize that increased synthesis of starch, lignin, or cellulose in stems or roots would normally be expected to strengthen the stem or root such that it would be less susceptible to breakage (reply page 8).

The Examiner disagrees that the specification enables a transgenic plant that is less susceptible to lodging, said plant comprising a gene of interest encoding a polypeptide that increases starch, lignin, or cellulose biosynthesis operably linked to the *SHORT-ROOT* promoter. While the specification may assert that genes that may be beneficially expressed in the stems of plant include those involved in starch, lignin or cellulose biosynthesis, and while one skilled in the art would recognize that increased synthesis of starch, lignin, or cellulose in stems or roots

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could strengthen the stem or root such that it would be less susceptible to breakage, the specification does not provide sufficient guidance for one skilled in the art to determine, without undue experimentation, which gene of interest encoding a polypeptide that increases starch, lignin, or cellulose biosynthesis to express under the control of the *SHORT-ROOT* promoter to achieve this effect, as the specification does not teach which of these genes, if any, the *SHORT-ROOT* promoter can express at a level sufficient to reduce the transgenic plant's susceptibility to lodging.

The rejection of claim 22 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of the transitional phrase "containing" is withdrawn in light of the amendment of claim 22.

Newly amended claims 22, 24, 31, 32 and 33, and claims 23 and 25 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "said promoter consisting essentially of", as it is unclear what would not materially affect the promoter function of the nucleic acid sequence of SEQ ID NO:4.

Claim Rejections - 35 USC § 102

Claims 31-33 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bevan et al. (GenBank Accession No. AL035605, March 4, 1999), for the reasons of record set forth in the office action mailed January 3, 2002.

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Applicant's arguments filed July 3, 2002, have been fully considered but they are not persuasive.

Applicant argues that Bevan et al. does not disclose an isolated nucleic acid molecule consisting essentially of SEQ ID NO:4, or an isolated nucleic acid molecule comprising a nucleic acid sequence which hybridizes over its full length under high stringency conditions to a *SHORT-ROOT* promoter which consists essentially of the nucleic acid sequence of SEQ ID NO:4 and which promotes stele-specific expression in the root or hypocotyl.

The Examiner maintains that Bevan et al. teach an isolated nucleic acid molecule having 100% sequence identity to SEQ ID NO:4. Because the isolated nucleic acid molecule taught by Bevan et al. has 100% sequence identity to SEQ ID NO:4, the Examiner maintains that the isolated nucleic acid molecule taught by Bevan et al. would necessarily hybridize over its full length under high stringency conditions to a *SHORT-ROOT* promoter which consists essentially of the nucleic acid sequence of SEQ ID NO:4. Additionally, because the isolated nucleic acid molecule taught by Bevan et al. has 100% sequence identity to SEQ ID NO:4, the Examiner maintains that the isolated nucleic acid molecule taught by Bevan et al. would inherently promote stele-specific expression in the root or hypocotyl.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

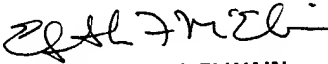
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
September 23, 2002


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800